

Multicenter, randomized, double-blind placebo controlled. Patients with active CD with CDAI 220-450 were randomized to GMA (granulocyte/monocyte apheresis) or sham procedure. Ten apheresis sessions were scheduled over a 9-week period.

Primary endpoint: Clinical remission (CDAI \leq 150) at week 12 without the use of prohibited drugs

Results: N=235

- Clinical remission was achieved by 17.8% GMA vs 19.2% sham control group, $p=0.858$
- Clinical response 28% GMA vs 26.9% sham control, $p=1$

Conclusion:

GMA was well tolerated, but this study did not demonstrate its effectiveness over a sham procedure in inducing clinical remission or response in patients with moderate to severe CD.

A randomised, double-blind, sham-controlled study of granulocyte/monocyte apheresis for moderate to severe Crohn's disease

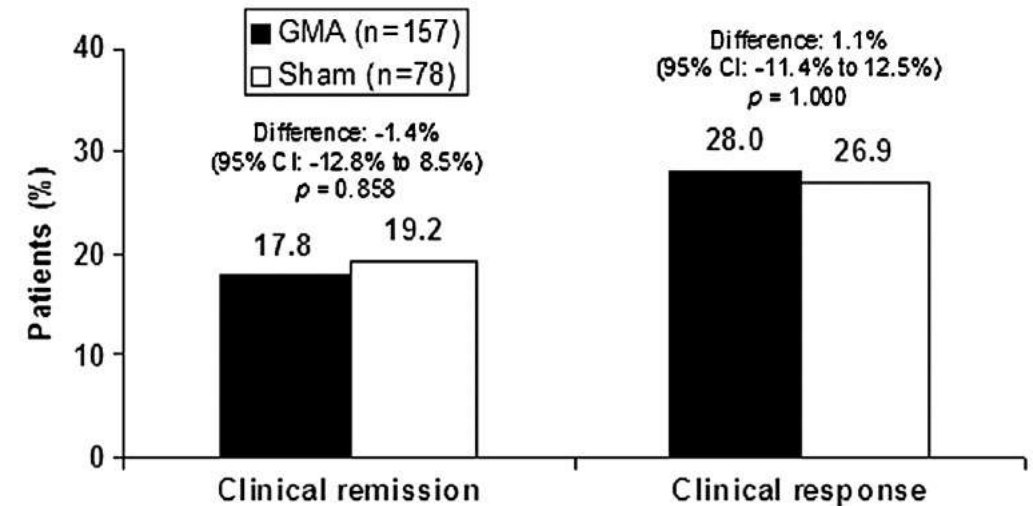


Figure 2 Clinical outcomes in patients treated with granulocyte/monocyte apheresis (GMA) and sham-treated patients.